

### **REMARKS**

Reconsideration of the rejections set forth in the Office Action mailed May 8, 2006, is respectfully requested. Claim 1 has been amended. Claims 1-19 remain pending. Support for this amendment can be found in the specification at, e.g., paragraphs [0227] - [0230]. Therefore, this amendment was made without introducing any new matter.

#### **Objections**

Claim 1 has been amended to provide antecedent basis for “a stenosis.”

#### **Art Rejections**

Claims 1-19 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Imran (USP 5,833,650). Applicants respectfully assert that Imran does not teach or suggest the steps of “*advancing an infusion catheter to a location distal to the stenosis*” and “*inducing retrograde flow within the blood vessel to carry the infused fluid [from the infusion catheter] and embolic material dislodged during the step of treating into the evacuation sheath assembly,*” as required by the amended claims.

Imran teaches two types of infusion. First, Imran teaches to introduce a saline solution “into the space immediately proximal of the stenosis 67 [sic]. This introduced saline solution aids the flow of particulate or other particles dislodged from the stenosis 76 during advancement of the guide wire 46 through the same and carries them back with the mixed saline blood solution through the aspiration lumen 26 in a manner hereinbefore described.” (emphasis added,

Col. 5, lines 56-63) In contrast, the claims require that the infusion catheter that delivers the infused fluid is located distal of the stenosis. Furthermore, it would not be obvious to one skilled in the art to modify the method of Imran to infuse the fluid distal of the stenosis because the purpose of infusing the saline in Imran is to aid in catching the particulate that is dislodged as the guide wire is advanced across the stenosis. Advancing an infusion catheter, which necessarily has a diameter larger than a guide wire, to a point distal the stenosis would create more emboli and would therefore be counterproductive.

Second, Imran teaches to infuse blood distal to the distal sealing balloon. (“[B]lood is shunted across the stenosis 76 and into the lumen 68 distal of the second balloon 36 by introducing blood through the fitting 38 and into the centrally disposed blood flow lumen 37 in the second tubular member 31 so that it exits out the central lumen 37 distal of the second balloon 36.” (Col. 6, lines 12-17) This step is to ensure that blood is being continuously supplied to the carotid artery of the patient during the time that the vessel is being occluded. (See Col. 6, lines 21-25) Claim 1, by contrast, requires that “the infused fluid and embolic material” be carried into the evacuation assembly, i.e., proximally, by retrograde flow. In Imran, there is no teaching or suggestion that a retrograde flow within the blood vessel is induced to carry the infused fluid and embolic material dislodged during the step of treating into the evacuation sheath assembly. In fact, because Imran teaches to fully occlude the vessel distal the lesion and proximal the point of infusion, e.g., Fig. 6D, Imran plainly intends to block retrograde flow of infused fluid into the catheter. Imran, therefore, *teaches away* from inducing a retrograde flow to carry the infused liquid back into the evacuation assembly because that would frustrate the purpose of continuously supplying blood to the carotid arteries in order to perfuse

and oxygenate tissue distal of the lesion while the vessel is occluded during the procedure.

Furthermore, it would not be obvious to one skilled in the art to modify the method of Imran to induce retrograde blood flow to carry the infused liquid and embolic material into the evacuation assembly. The multiple sealing balloons of the Imran device are used to create a “working space” such that “medical procedures can be undertaken to remove or reduce the stenosis 76 in the space between the first and second balloons 19 and 36.” (Col. 6, lines 26-31) The infusion of blood is for the purpose of perfusion through this isolated space to the distal tissues, not evacuation of debris created in this space. The distal sealing balloon prevents any particulate from escaping upstream of the stenosis. Therefore, there is no need to induce retrograde blood flow to carry the infused liquid and embolic material into the evacuation assembly.

Claims 2-19 depend from claim 1 are patentably distinct for the same reasons as applicable to claim 1. Therefore, Applicants respectfully request withdrawal of the rejections and reconsideration of the claims as amended.

Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicant's undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,  
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